In re Application of: Gad KEREN et al
Serial No.: 09/839,643
Filed: April 20, 2001
Office Action Mailing Date: November 12, 2009
Examiner: NGUYEN Camtu Tran
Group Art Unit: 3772
Attorney Docket: 34948
Confirmation No.: 2139

REMARKS

Reconsideration of the above-identified application in view of the amendments above and the remarks following is respectfully requested.

Claims 49-51, 59, 60, 68-73, 78, 84, 86-89, 92 and 97-108 are pending in the application. Claims 49-51, 59, 60, 68-73, 78, 84, 86-89, 92 and 97-108 are rejected.

Claims 59, 69, 73, 78, 89 and 103 have now been amended. Claims 60 and 71-72 have now been cancelled.

Claim Rejections - 35 USC § 101

The Examiner has rejected claims 49, 59, 84 and 103 under 35 USC 101 because the claimed invention is directed to non-statutory subject matter.

Specifically, the Examiner states that these claims recite language that positively set the claimed devices on the human body.

Claims 49 and 84 are method claims and as such recite steps required for implanting the device in heart tissue. Specifically, claim 49 recites "implanting a shunt between a left atrium and a right atrium of the heart" while claim 84 recites "implanting a valve in a heart septum between two heart atria". Applicant believes that in the context of method claims, such recitations do not positively claim a portion of a human body but rather identify the anatomical region of a human body which is targeted by the claimed methods.

Claims 59 and 103 which are directed at devices have now been amended to recite that the device (shunt) is "configured for positioning" rather than --being positionable--.

Applicant believes that amended claims 59 and 103 do not positively claim a portion of a human body and as such no longer constitute non-statutory subject matter.

Claim Rejections - 35 USC § 112

The Examiner has rejected claim 89 under 35 USC 112, second paragraph, as being indefinite.

The Examiner states that blood flow would not lead to a ventricle when a valve is implanted between two atria.

Claim 89 has now been amended to correctly recite "a right atria of said heart".

Claim Rejections - 35 USC § 102

The Examiner has rejected claims 49-51, 59-60, 71, 84, 86-89, 90, 92, 97-102, under 35 U.S.C. 102(e) as being anticipated by Wilk (U.S. Patent No. 7,294,115).

The Examiners rejections are respectfully traversed. Claims 49 and 59 have now been amended.

The Examiner states that Wilk discloses (in Figures 1-5) shunts with valves in a heart wall from a ventricle to the coronary artery, but also describes that such shunts with valves can be applied to the right and left atria (Column 11, lines 64-67).

Wilk teaches "Methodology and related medical devices for effectively bypassing a blocked or partially blocked coronary artery and providing oxygenated blood to the myocardium" (abstract). Wilk does not teach or suggest methods and devices for decreasing blood pressure in a heart chamber, by routing blood from one chamber (left atria) to an adjacent chamber (right atria) through the septum separating these chambers.

Reduction of left atrial pressure can be used to offset abnormal hemodynamics characterizing CHF and other heart pathologies and thus can be used to treat disorders, such as, for example, pulmonary edema. Pulmonary edema develops when an imbalance in the heart pumping function causes an increase in lung fluid secondary to leakage from pulmonary capillaries into the interstitium and alveoli of the lung.

The object of the invention described by Wilk is routing of blood from a ventricle to a coronary artery for the purpose of bypassing a blockage in such an artery and restoring blood supply to ischemic heart tissue. Wilk does not suggest treatment of abnormal heart hemodynamics. In addition, none of the Figures or descriptions provided by Wilk illustrate or suggest approaches suitable for reduction of left atrial pressure.

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Column 11, lines 64-67 of Wilk recites the following:

"In a transmyocardial coronary artery bypass operation illustrated in FIGS. 1A 1E, a catheter 12 is inserted over a guidewire (not illustrated) through the vasculature of a patient and particularly through the aorta AO into the left ventricle LV of the patient's heart PH. (Although the embodiments described herein are discussed with respect to the left ventricle LV, they may also be applied to the right ventricle RV and the right and left atria.) (Emphasis added)

These teachings of Wilk refer to alternative catheter routing approaches. As is well known in the art, catheters used for percutaneous treatment of heart tissue can be routed to the target tissue using several different navigational approaches depending on the target tissue and access site used.

Thus, Wilk is simply referring to catheter routing options which can be used to guide the catheter "through the vasculature of a patient and particularly through the aorta AO into the left ventricle LV of the patient's heart", or through other chambers such as the right ventricle or right and left atria.

Although this excerpt from Wilk can also be interpreted to imply that these other chambers can be used as a source of blood for the bypassed artery (highly unlikely), the device of Wilk and the implantation approach described thereby necessitate that one end of Wilk's shunt always open into an artery downstream of the blockage, regardless of where the opposite end of the shunt is placed (source), since the object of Wilk's invention is to create a bypass, and not to route blood from one chamber to the next through the septum.

Since Wilk does not describe or suggest atrial-atrial conduits for the purpose of relieving abnormal left atrial pressures, it is clear that any mention of an atrium in Wilk is done with reference to catheter navigation or (though highly unlikely) a source end of shunt which ultimately terminates in an artery downstream of an obstruction.

Notwithstanding from the above, in order to further distinguish the present invention as claimed from the teachings of Wilk, Applicant has elected to amend claim 49 to recite: "implanting a shunt between a left atrium and a right atrium of the heart, such that a first end of said shunt resides in said left atrium and a second end of said shunt resides in said right atrium".

The teachings of Wilk do not describe or suggest such methodology or a shunt useful for such purposes. Furthermore, Wilk does not describe nor suggest a need for "enabling blood flow between said left atrium and said right atrium and decreasing blood pressure in an atrium".

In addition, Wilk does not teach or suggest implantation of a valve in a septum separating the atria (claim 84). Such an approach, which is clearly designed for enabling controlled flow between the atria is not described or suggested by Wilk, which as described above, teaches methods of bypassing blocked arteries via shunts/valves positioned in the myocardium.

In light of the above arguments and the amendments to claim 49, Applicant believes that the method claims now pending in the application are neither anticipated nor rendered obvious by the teachings of Wilk.

The Examiner also rejected device claim 59 as being anticipated by Wilk.

Claim 59 has now been amended to include a valve which is "configured for opening when a pressure differential between said left atrium and said right atrium is 12 mmHg or above.

Such valve functionality is neither described nor suggested by Wilk and in fact would be counterproductive in the shunts of Wilk which can employ valves but only for preventing backflow from the artery and not limiting flow into the artery.

In fact, Wilk repeatedly mentions that "flow control is achieved by maximizing flow through the conduit in one direction (preferably from the left ventricle to the coronary artery), but minimizing flow through the conduit in the opposite direction."

It will be appreciated that a valve capable of enabling flow at a pressure differential of 12 mmHg or more is particularly advantageous for use with the present

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invention, since shunting of blood from the left atrium to the right atrium is only desired during periods of excessive pressure differential (12 mmHg or over) and not during periods of normal pressure differentials (less than 12 mmHg). In fact, shunting of blood under normal pressure differentials could lead to too much flow across the valve and an unacceptable reduction in cardiac output.

Thus, under normal pressure differentials, the valve remains closed to ensure that cardiac output is not substantially reduced, while under excessive pressure differentials (caused by excessive pressures in the left atrium), the valve opens and enables flow between the left and right atria and reduction of pressure in the left atrium. Although such temporary shunting may result in some reduction in cardiac output, without shunting, left atrial pressure buildup would result in backflow of blood into the lungs and acute cardiogenic pulmonary edema.

Applicant believes that now amended claim 59 is neither anticipated nor rendered obvious by the teachings of Wilk.

The Examiner has also rejected claims 59-60, 68-71, 73 and 78 under 35 U.S.C. 102(e) as being anticipated by Bailey et al.

The Examiner states that with respect to claim 59, Bailey et al's stent valve (4) is positioned through a septum mitral valve, hence it is clearly capable of being positionable within a septum between atria.

The valve described by Bailey et al. would be incapable of the functionality of the valve of the device of now amended claim 59.

The valve of Bailey et al. is configured for opening under atrial systolic pressure, as is clearly recited on column 11, lines 16-23:

"Turning to FIGS. 12A and B there is illustrated the inventive CC stent valve 40 implanted in the position of the mitral valve and excluding the anatomic mitral valve MV. FIG. 12A illustrates the heart during atrial systole in which a positive pressure is applied to the prosthetic mitral valve by contraction of the left atrium LA and the pressure exerted by the blood flow represented by the arrow. The atrial

systolic pressure overcomes the bias exerted by the valve arms 24 onto the valve leaflets 26, and causes the valve leaflets 26 to open and release the atrial ejection fraction into the left ventricle. "

Since the valve utilized by Bailey et al. is designed to replace the natural A-V valve, it would be designed to provide the same functionality of a natural valve and as such it would be incapable of resisting any pressure differential between the atrium and ventricle, let alone the 12 mmHg pressure differential or more required for initial opening of the valve utilized by the present device.

Initial opening of a natural A-V valve occurs at a negligible pressure differential which is close to 0 mmHg (see http://en.wikipedia.org/wiki/File:Cardiac_Cycle_Left_Ventricle.PNG) and as such, any functional equivalent of the A-V valve, i.e. the device of Bailey et al., would be incapable of staying completely closed even under minimal pressure differentials (<1 mmHg) between the left atria and the left ventricle.

Thus, the device of Bailey et al. (and in fact any valve designed for A-V functionality) could not be effectively used to treat CHF patients having excessive left atrial pressure buildup since it would permit undesired flow between atria even under near zero pressure differentials which would result in severely diminished cardiac output, a highly undesirable condition especially in CHF patients.

As such, the teachings of Bailey et al. do not anticipate or render obvious the present invention as claimed.

Claim Rejections - 35 USC § 103

The Examiner has rejected claims 72 and 103 under 35 U.S.C. 103(a) as being unpatentable over Bailey et al. in view of Wolf et al. (U.S. Patent No. 6,641,610).

The Examiner has also rejected claims 104-108 as being unpatentable over Bailey et al./Wolf et al. (U.S. Patent No. 6,641,610) and further in view of Cosman (U.S. Patent No. 4,787,886).

As is argued hereinabove, Bailey et al. do not describe nor suggest the presently claimed device and method. Wolf et al. merely describe a one way valve utilizable in bypass conduits, while Cosman describes a pressure sensor which the Examiner suggests can be used in combination with the device of Bailey et al.

Applicant fails to understand what technical problem one would attempt to solve by combining the teachings of Wolf/Cosman with those of Bailey et al. The valve of Bailey et al. is clearly designed to work under normal pressure conditions present in the atrium and thus it would not benefit from any changes to such functionality.

Since the teachings of Wolf et al. and Cosman are not relevant to the use and function of the device of Bailey et al., Applicant is of the opinion that the present invention as claimed is patentable over the combined teachings of Bailey et al. and Wolf et al. or Bailey et al./Wolf et al. and Cosman.

In view of the above amendments and remarks it is respectfully submitted that claims 49-51, 59, 68-70, 73, 78, 84, 86-89, 92 and 97-108 are now in condition for allowance. A prompt notice of allowance is respectfully and earnestly solicited.

Respectfully submitted,

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